



e) an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen, or

- whereby X with R1 forms an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen.

Claim 4. (Previously Presented): Process according to claim 3, wherein the substituents are selected from the group consisting of alkyl, carboxyl, alkoxy groups, hydroxy groups, and aryl groups which optionally contain alkyl, carboxyl, alkoxy or hydroxy groups, or are amino groups, monoalkyl- or monoaryl-amines, dialkyl- or diaryl-amines, a trialkylammonium or triarylammonium group, a cyclic amine or a basic heterocycle.

Claim 5. (Previously Presented): Process according to claim 4, wherein the substituents stem from the groups n-butylamine, ethylenediamine, diaminobutane, diaminopentane, diaminohexane, diaminocyclohexane, or dimethylaminopropylamine, for example 3-N,N-dimethylamino-1-propylamine.

Claim 6. (Previously Presented): Process according to claim 1 wherein the primary or secondary amine is soluble in an organic solvent.

Claim 7. (Previously Presented): Process according to claim 6, wherein the organic solvent is selected from the group consisting of a ketone, a nitrile, and an inert solvent, optionally in the presence of a cosolvent, or mixtures thereof.

Claim 8. (Previously Presented): Process according to claim 7, wherein the inert solvent is an acetic acid (C1-C4)-alkyl ester or a halogenated hydrocarbon, optionally in the presence of a cosolvent.

Claim 9. (Previously Presented): Process according to claim 7 wherein the inert solvent is ethyl acetate, isopropyl acetate or dichloromethane, optionally in the presence of a co-solvent.

Claim 10. (Previously Presented): Process according to claim 7 wherein the cosolvent is an organic amide.

Claim 11. (Withdrawn): Process for the purification of mycophenolate mofetil, comprising:

- a) activation of mycophenolic acid by forming a reactive derivative in an inert solvent,
- b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,

- c) treating it with a primary or secondary amine, and
- d) isolating the mycophenolate mofetil.

Claim 12. (Withdrawn): Process for the purification of mycophenolate mofetil, which contains by-products, characterised in that it comprises the following reaction steps:

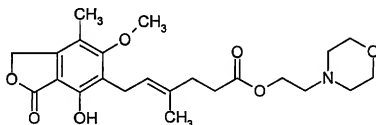
- a) preparing a solution or suspension of mycophenolate mofetil as a free base in an inert solvent,
- b) treating it with a primary or secondary amine, and
- c) isolating the mycophenolate mofetil.

Claim 13. (Withdrawn): Process according to claim 12, wherein the by-products contain dimers.

Claim 14. (Withdrawn): Mycophenolate mofetil as the free base with a maximum content of dimers of 0.15% (area percent HPLC).

Claim 15. (Withdrawn): Mycophenolate mofetil as the free base with a content of dimers of 0.15 to 0.03% (area percent HPLC).

Claim 16. (Withdrawn): Process for the production of mycophenolate mofetil of formula



wherein a reactive derivative of mycophenolic acid is produced in an inert solvent and is reacted with 4-(2-hydroxyethyl)morpholine, and the resulting mycophenolate mofetil is isolated from the reaction mixture, wherein

- I) 4-(2-hydroxyethyl)morpholine is added under controlled conditions to the solution of the reactive derivative of mycophenolic acid, whereby the reaction takes place under acidic reaction conditions, and
- II) isolation of mycophenolate mofetil is effected by forming an acid addition salt and subsequently releasing the free base.

Claim 17. (Withdrawn): Process according to claim 16, which additionally comprises:

- a) activation of mycophenolic acid by forming a reactive derivative

b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,

c) isolating mycophenolate mofetil through the formation of an acid addition salt, and

d) releasing the free base of mycophenolate mofetil from the acid addition salt.

Claim 18. (Withdrawn): Process according to claim 11, wherein the reactive derivative of mycophenolic acid is an acid halide.

Claim 19. (Withdrawn): Process according to claim 18, wherein the acid halide is an acid chloride.

Claim 20. (Withdrawn): Process according to claim 16 wherein the acid addition salt of mycophenolate mofetil is the oxalate or the hydrochloride of mycophenolate mofetil.

Claim 21. (Withdrawn): Process according to claim 16 comprising the following process steps:

a) activation of mycophenolic acid by forming a reactive derivative,

b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,

c) treating the reaction mixture with a primary or secondary amine,

d) isolating mycophenolate mofetil through the formation of an acid addition salt, for example the oxalate, and

e) releasing the free base of mycophenolate mofetil from the acid addition salt.

Claim 22. (Withdrawn): Process for the purification of mycophenolate mofetil, comprising:

a) preparing a solution or suspension of mycophenolate mofetil as an acid addition salt in an inert solvent,

b) releasing the free base,

c) treating it with a primary or secondary amine, and

d) isolating the mycophenolate mofetil.

Claim 23. (Withdrawn): Process according to claim 22, wherein the acid addition salt of mycophenolate mofetil is the oxalate or the hydrochloride of mycophenolate mofetil.

Claim 24. (Withdrawn): Mycophenolate mofetil as the oxalate with a maximum content of dimers of 0.1% (area percent HPLC).

Claim 25. (Withdrawn): Mycophenolate mofetil as the oxalate with a content of dimers of 0.1 to 0.03% (area percent HPLC).

Claim 26. (Previously Presented): Process according to claim 1 wherein the maximum amount of dimer by-products in the purified mycophenolate mofetil is 0.1% (area percent HPLC).